GUAIFENESIN DM- guaifenesin and dextromethorphan solution
Pharmaceutical Associates, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Maximum Strength
Guaifenesin DM
Non-Narcotic, Sugar and Alcohol Free
Expectorant/Cough Suppressant

Drug Facts

Active ingredients (in each 5 mL teaspoonful)	***Purposes***
Guaifenesin 200 mg	Expectorant
Dextromethorphan HBr 10 mg	Cough Suppressant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Stop use and ask a doctor if cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- shake well before using
- do not take more than 6 doses in any 24-hour period

age	dose
adults and children 12 years and over	10 mL (2 teaspoonsful) every 4 hours
children 6 to under 12 years of age	5 mL (1 teaspoonful) every 4 hours
children 2 to under 6 years of age	2.5 mL (1/2 teaspoonful) every 4 hours

children under 2 years	consult a doctor

Other information

- **each teaspoonful contains:** sodium 4 mg
- store at 20° - 25°C (68° - 77°F)
- alcohol/sugar free
- red, cherry flavored solution supplied in the following oral dosage forms: *NDC* 0121-0809-04 (4 fl oz bottle), *NDC* 0121-0809-08 (8 fl oz bottle), *NDC* 0121-4809-05 (unit dose cups of 5 mL, packaged in trays of 10), and *NDC* 0121-4809-10 (unit dose cups of 10 mL, packaged in trays of 10).

Inactive ingredients

Acesulfame K, citric acid, FD&C Red No. 40, flavoring, glycerin, menthol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol and sucralose.

Questions or comments?

Call 1-800-845-8210. You may also report serious side effects to this phone number.

PRINCIPAL DISPLAY PANEL - 118 mL Label

NDC 0121-0809-04

Quality®
Value

Maximum Strength

Guaifenesin DM

Cough & Chest
Congestion

DEXTROMETHORPHAN HBr (Cough Suppressant)
GUAIFENESIN (Expectorant)

ALCOHOL / SUGAR FREE
Relieves Cough /
Maximum Strength
Mucus Relief

4 fl oz (118 mL)

PRINCIPAL DISPLAY PANEL - 5 mL Lid

Delivers **5 mL**
NDC 0121-4809-05

MAXIMUM STRENGTH
GUAIFENESIN DM

Guaifenesin (Expectorant)
Dextromethorphan HBr (Cough Suppressant)

200 mg/10 mg per 5 mL

Alcohol Free / Sugar Free

FOR INSTITUTIONAL USE ONLY
PHARMACEUTICAL ASSOCIATES, INC.
GREENVILLE, SC 29605
SEE INSERT

GUAIFENESIN DM

guaifenesin and dextromethorphan solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-0809
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 5 mL
DEXTROMETHORPHAN (UNII: 7355X3ROTS) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN	10 mg in 5 mL

Product Characteristics			
Color	RED	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0121-0809-08	237 mL in 1 BOTTLE		
2	NDC:0121-0809-04	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/17/2010	

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Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-4809-05	4 in 1 CASE		
1		10 in 1 TRAY		
1		5 mL in 1 CUP, UNIT-DOSE		
2	NDC:0121-4809-10	4 in 1 CASE		
2		10 in 1 TRAY		
2		10 mL in 1 CUP, UNIT-DOSE		

Marketing Information

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OTC monograph final	part341	05/17/2010	

Labeler - Pharmaceutical Associates, Inc. (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		044940096	MANUFACTURE

Revised: 2/2010 Pharmaceutical Associates, Inc.